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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/091,665 09/02/98 ENDRIKAT

J SCH1637

HM12/0815  
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EXAMINER

GAZI, S

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

08/15/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/091,665**

Applicant(s)

**Endrikat et al.**

Examiner

**Sabiha Qazi**

Group Art Unit

**1616**



☒ Responsive to communication(s) filed on Jun 29, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-30 is/are pending in the application.

Of the above, claim(s) 8-12 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-7 and 13-30 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 8-12 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 9

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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***Office Action on Merits***

***Invention:*** Instant invention is drawn to the contraceptive process and administering gestagen, estrogen and/or the combination thereof.

***Status of the application***

Claims 1-30 are pending.

Claims 1-7 and 13-30 are rejected.

Claims are withdrawn from consideration as non elected invention.

No claim is allowed.

***Rejection Withdrawn***

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gast and Koninckx (US Patent 5,747,480 and US 5,827,843). See lines 5-67, col. 2, examples 1-7, col. 3 and 4; claims 1-9. Of '843; lines 8-67, col. 7; lines 26-67, col. 8; lines 1-30, col. 9, examples 1 and 2, cols 9 and 10; claims 1-26 are withdrawn because claims are now amended.

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### **Response to Arguments**

Applicant's arguments were fully considered but are not found persuasive. The basis of the arguments is that the search for the entire invention would not be a burden on Examiner. Examiner respectfully disagree for the following reasons.

Since each group belongs to different and separate inventions, and a reference used to reject one group will not be used to reject the other group.

I. Claims 1-7 and 13-30 are drawn to a contraceptive process, classified in class 514, subclass 182, 841, 843, 179.

II. Claims 9-12 are drawn to kits, classified in class 514, subclass 170, 182, 841, 843; class 424, subclass 464; class 206.

The inventions listed as Groups I and do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Claims 1-7 and 13-30 are drawn to the method of contraceptive process by administering a combination of gestagen and natural estrogen. Claims 9-12 are drawn to kits which would

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require different searches. It would be a burden on the examiner to search the whole invention as claimed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. The search for the entire invention as instantly claimed would be a burden on the Examiner. Restriction is made FINAL.

Applicant's arguments about 103 rejection was considered. The invention is considered obvious because the application for different days or periods would have been obvious to a person who is familiar with art. Applicant's should show side by side comparison of any unexpected results if there invention is different and better than the prior art. See MPEP 716.02 (e).

**Rejection Maintained**

1. Claims 1-7 and new claims 13-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuman, Friedmund (CA 118:161077, abstract of Pharm. Ztg. (1992), 137(34), 9-15) and over Gast and Koninckx (US Patent 5,747,480 and US 5,827,843) for the same reasons set forth in office action mailed in paper no. 8.

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**New Ground of rejection**

1. Claims 1-7 and 13-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Jager et al. (CA 2000438). The reference teaches the combination preparation of estrogen and progestagen which embraces applicant's claimed subject matter. See the entire document especially first para on page 5, where gestrogens, desogestrel, gestoden are listed, which are the same as instantly claimed. See also example III on page 9, which is the combination of desogestrel with oestradiol.

Instant invention is drawn to a method of contraception by administering gestagen, estrogen and/or the combination thereof.

Instant claims differ from the reference in claiming different sequential and duration of the treatment.

It would have been obvious to one skilled in the art at the time of invention to use gestagen, estrogen or the combination of both for the conception as instantly claimed particularly when prior art teaches the combination of gestagen and estrogen for the same purpose. There has been ample motivation provided by the prior art to prepare the instant invention. The combination by selection the gestagens and estrogen would have been obvious at the time of invention.

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The determination to employ the optimum proportion, duration or combination of the ingredients as cited in claims would have been within the skills of the one familiar with the art. These numerical limitations of the molar ratios recited in claims of the instant invention do not distinguish the claims over the prior art because they would have been obvious to one skilled in the art in the absence of a showing of criticality, of unobviousness or unexpected results over the prior art.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by

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the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

The data showing any unexpected results would overcome the above 35 U.S.C. 103(a) rejection.

***Telephone Inquiry Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



**Sabiha N. Qazi Ph.D.**

**Examiner,**

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**8/13/00**